



P/546-279

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of

WILLIAM STERN

Date: September 22, 2006

Serial No.: 10/774,358 (Reissue of USP 6,440,392)

Group Art Unit: 1616

Filed: February 5, 2004

Examiner: Mina Haghighatian

For: NASAL CALCITONIN FORMULATION

-----  
Mail Stop Reissue  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. §1.178(b)**

Sir:

**Introductory Comments**

Pursuant to 37 C.F.R. § 1.178(b) and M.P.E.P. 1442.04, Applicant submits this paper to provide information regarding:

- (1) a concurrent litigation involving U.S. Patent No. 6,440,392, which patent is the subject of this Reissue application;
- (2) information sufficient to allow the Office to reasonably evaluate the need for requesting further materials; and
- (3) descriptions and copies of supporting materials.

**I. Concurrent Litigation**

As noted above, this is an application for reissue of U.S. Patent No. 6,440,392 ("the '392 Patent). The '392 Patent is involved in the following concurrent litigation:

00788177.1

09/28/2006 HDESTA1 00000085 10774358

02 FC:1806

180.00 OP

*Unigene Laboratories, Inc. and Upsher-Smith Laboratories, Inc. v. Apotex, Inc. and Apotex Corp.* (hereinafter referred to collectively as “Apotex”), in the United States District Court for the Southern District of New York, Civil Action No. 06-cv-5571-RPP-THK (ECF Case). A copy of the Complaint filed by Plaintiffs in this matter is appended hereto. The Complaint includes, as Attachment A, a copy of the ‘392 Patent under reissue. The Complaint is, in addition, listed on the Form PTO-1449 submitted with this Information Disclosure Statement.

## **II. The Notice Letter**

Plaintiffs have received a so-called “Notice Letter” dated June 1, 2006 from Apotex, Inc. pursuant to Section 505(j)(2)(B) (i) and (ii) of the Federal Food, Drug and Cosmetic Act. A copy of the Notice Letter is provided herewith. The letter is also listed on the accompanying Form PTO-1449. The Notice Letter contains allegations relating to the validity and enforceability of the ‘392 Patent.

### **A. Allegations Based on Prior Art**

Apotex has made allegations against the validity of the ‘392 Patent in the Notice Letter. In particular, pps. 3-9 of the Notice Letter contains arguments by Apotex that one or more of the claims of the ‘392 Patent are invalid in light of the disclosure of one or more prior art references that are discussed therein. All but one such reference (copy enclosed herewith and cited on the Form PTO-1449) was already of record in this Reissue.

### **B. Allegations of Inequitable Conduct**

Allegations are also raised by Apotex at pps. 9-10 of the Notice Letter that the ‘392 Patent is unenforceable due to inequitable conduct by the applicant during prosecution of the ‘392 Patent. Applicant denies that any inequitable conduct occurred.

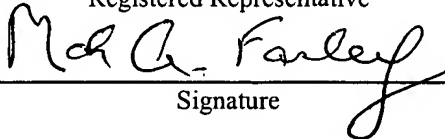
The information provided herein is submitted for consideration by the Examiner in connection with this application for reissue, and to allow the Examiner to consider the need for requesting additional information.

Check No. 25800 which includes a \$180.00 fee for the submission of this Information Disclosure Statement, is enclosed herewith. In the event the actual fee is greater than the payment submitted or is inadvertently not enclosed, or if any additional fee during the prosecution of this reissue application is not paid, the Patent Office is authorized to charge the underpayment to Deposit Account No. 15-0700.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Reissue, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on September 22, 2006:

Mark A. Farley

Name of applicant, assignee or  
Registered Representative

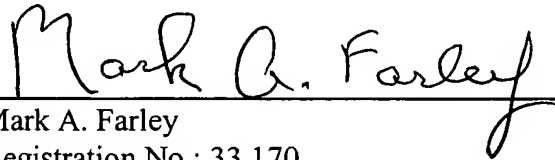


Signature

September 22, 2006

Date of Signature

Respectfully submitted,



Mark A. Farley

Registration No.: 33,170

OSTROLENK, FABER, GERB & SOFFEN, LLP

1180 Avenue of the Americas

New York, New York 10036-8403

Telephone: (212) 382-0700

WOG:MAF:jl/db



APPLICANT'S ART CITATION

(Use several sheets if necessary)

Application 10/774,358

OFGS File No. P/546-279

Applicant WILLIAM STERN

Filing Date February 5, 2004

Group Art Unit 1616

U.S. PATENT DOCUMENTS (not submitted for applications filed after 6/30/03)

Examiner Initial	Document Number	Date MM- YYYY	Name	Class	Sub- class	Filing Date If Appropriate
	US- 5,514,365	05-1996	Mardente, et al.	424	45	
	US-					
	US-					
	US-					
	US-					
	US-					
	US-					

FOREIGN PATENT DOCUMENTS

	Document Number	Date MM- YYYY	Country	Class	Sub- class	Translation	
						Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Apotex Notice Letter - June 1, 2006
	Complaint by <i>Unigene Laboratories, Inc., et al. v. Apotex, Inc., et al.</i> , 06-cv-5571-RPP-
	THK (EFC Case) - U.S. District Court for the Southern District of New York

Examiner

Date Considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.